EXHIBIT A

UNITED STATES DISTRICT COURT

for the

District of Delaware

Amgen Inc.

Plaintiff

v.

Sandoz Inc.

Defendant

Civil Action No.

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTION

To: Persons most knowlegeable at Sandoz Inc.
C/O Corporation Services Company, 251 Little Falls Drive, Wilmington, Delaware 19808

(Name of person to whom this subpoena is directed)

☑ *Production:* **YOU ARE COMMANDED** to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See Attachment A hereto

Place:	Date and Time:
Morris, Nichols, Arsht & Tunnell LLP 1201 North Market Street P.O. Box 1347; Wilmington, DE 19899-1347	05/30/2023

❒ *Inspection of Premises:* **YOU ARE COMMANDED** to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 05/09/2023

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

/s/ Brian P. Egan
Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing *(name of party)* Amgen Inc. , who issues or requests this subpoena, are:

Brian P. Egan (#6227); began@morrisnichols.com; 1201 North Market Street; P.O. Box 1347; Wilmington, DE 19899-1347

Notice to the person who issues or requests this subpoena

A notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this subpoena for *(name of individual and title, if any)* _____

on *(date)* _____ .

❒ I served the subpoena by delivering a copy to the named person as follows: _____

_____

_____ on *(date)* _____ ; or

❒ I returned the subpoena unexecuted because: _____

_____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of $ _____ .

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc.:

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

(1) ***For a Trial, Hearing, or Deposition.*** A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
(i) is a party or a party's officer; or
(ii) is commanded to attend a trial and would not incur substantial expense.

(2) ***For Other Discovery.*** A subpoena may command:
(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
(B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) ***Avoiding Undue Burden or Expense; Sanctions.*** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) ***Command to Produce Materials or Permit Inspection.***
(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.
(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) ***Quashing or Modifying a Subpoena.***
(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:
(i) fails to allow a reasonable time to comply;
(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
(iv) subjects a person to undue burden.
(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
(i) disclosing a trade secret or other confidential research, development, or commercial information; or
(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) ***Producing Documents or Electronically Stored Information.*** These procedures apply to producing documents or electronically stored information:
(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.
(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) ***Claiming Privilege or Protection.***
(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
(i) expressly make the claim; and
(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.
The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

For access to subpoena materials, see Fed. R. Civ. P. 45(a) Committee Note (2013).

ATTACHMENT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE THE APPLICATION OF AMGEN INC.	)	Misc. Case. No. _____

SUBPOENA TO SANDOZ INC. TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS IN A CIVIL ACTION

DEFINITIONS

The following definitions are applicable to the identification of documents that are the subject of this subpoena:

1. The terms "you," "your," and "Sandoz" mean Sandoz Inc., and any parent, subsidiary, member and/or affiliated entity, past or present, of Sandoz, and any person or entity, past or present, acting on behalf of Sandoz, including, but not limited to, each of its present and former managers, officers, executives, directors, employees, attorneys, agents and/or representatives.

2. "Amgen" means Amgen Inc.

3. "Sandoz Austria" means collectively, jointly, and severally Sandoz GmbH and its officers, directors, representatives, employees, agents, partners, corporate parents, subsidiaries, affiliates, predecessors and successors, including any entities or persons acting on behalf of Sandoz Austria.

4. "Sandoz Slovenia" means collectively, jointly, and severally Lek Pharmaceuticals d.d. (Lek farmacevtska družba d.d.) and/or Novartis Pharmaceutical Production d.o.o. (Novartis farmacevtska proizvodnja d.o.o.) and their officers, directors, representatives, employees, agents, partners, corporate parents, subsidiaries, affiliates, predecessors and successors, including any entities or persons acting on behalf of Sandoz Slovenia.

5. "Prolia®" means Amgen's product that contains the RANKL inhibitor antibody denosumab that is marketed under the Prolia brand name.

6. "XGEVA®" means Amgen's product that contains the RANKL inhibitor antibody denosumab that is marketed under the XGEVA brand name.

7. "Sandoz's Biosimilar Product" means any and all denosumab that Sandoz develops, manufactures, markets, or sells, or seeks to develop, manufacture, market, or sell, including denosumab products that are biosimilar to Prolia® and/or XGEVA®.

8. "EMA" means the European Medicines Agency.

9. "FDA" means the U.S. Food and Drug Administration.

10. "Document" shall be defined and construed in the broadest possible sense by Rule 34(a) of the Federal Rules of Civil Procedure and other applicable Rules, and includes papers of all kinds and non-paper information storage means, including by way of example and without limitation, originals and copies, however made, of letters, memoranda, notes, computer generated data, calendars, records, minutes, studies, reports, notebooks, messages, telegrams, ledgers, legal instruments, contracts (whether draft or final), agreements (whether draft or final), drawings, secretarial notes, work pads, diaries, films, tapes, videotapes, CD's, CVD's, pictures, photographs, books, pamphlets, publications, advertisements, sales literature, brochures, manuals, price lists, computer files, announcements, electronic mail messages, or any other writings,

records, or tangible objects produced or reproduced mechanically, electrically, electronically, photographically, or chemically. A draft or non-identical copy is a separate document within the meaning of this term.

11. "Communication" shall have the broadest possible meaning and shall include, without limitation, any transmission of information by one or more persons or entities and/or between two or more persons or entities by any means, including but not limited to all documents reflecting, recording, reporting, or memorializing or purporting to reflect, record, report, or memorialize any such communication.

12. The term "thing" means any physical specimen or other tangible item other than a document.

13. The terms "referring to," "relating to," or "concerning" shall encompass the full scope allowed under Rule 26 of the Federal Rules of Civil Procedure, and mean in any way, directly or indirectly, regarding, considering, constituting, covering, defining, describing, involving, underlying, modifying, amending, confirming, mentioning, endorsing, recording, evidencing, pertaining to, referring to, reflecting, relating to, representing, supporting, qualifying, terminating, revoking, canceling, negating, or having any connection with the matter discussed.

14. The terms "and" and "or" shall be interpreted liberally as conjunctive, disjunctive, or both so that the fullest disclosure of information is achieved.

15. The term "all" means all and each and the term "each" means each and all so that the fullest disclosure of information is achieved.

16. The singular includes the plural and the plural includes the singular so that the fullest disclosure of information is achieved.

17. The term "including" means including, but not limited to.

INSTRUCTIONS

1. Sandoz is requested to respond within 21 days from the date of service of this subpoena and the Court's order authorizing service of this subpoena.

2. These discovery requests shall be deemed continuing, requiring Sandoz to serve supplemental answers and documents and things promptly if Sandoz obtains additional documents and things, particularly if Sandoz learns that in some material respect that its prior disclosure or response is incomplete or incorrect. *See* Fed. R. Civ. P. 26(e).

3. If Sandoz has a good faith objection to any request or any part thereof, the specific nature of the objection and whether it applies to the entire request or to a part of the request shall be stated. If there is an objection to any part of a request, then the part objected to shall be identified and documents responsive to the remaining unobjectionable part of the request shall be produced.

4. Each request shall be answered on the basis of Sandoz's entire knowledge, from all sources, after an appropriate good faith inquiry has been made and a search has been conducted.

5. If Sandoz withholds information on the grounds of attorney-client privilege, work product immunity or any other privilege or immunity, Sandoz must identify the nature of the privilege which is being claimed, and if the privilege is being asserted in connection with a claim or defense governed by state law, set forth the state privilege rule being invoked; and must provide:

a) the type of document, e.g., letter or memorandum;

b) the general subject matter of the document;

c) the date of the document; and

d) such other information as is sufficient to identify the document, including where appropriate, the author of the document, the addressees of the document, and any other

recipients shown in the document, and where not apparent, the relationship of the author, addressees, and recipients to each other.

6. If Sandoz contends that information responsive to any discovery request is incomplete, then Sandoz must provide all responsive information of which Sandoz is now aware.

7. For any document requested herein that has been destroyed, transferred or lost, Sandoz shall identify the document and provide a brief explanation of the circumstances (e.g. when, how, by whom, and why) surrounding the document's destruction, transfer or loss, and any and all records pertaining to its destruction, transfer or loss.

8. If Sandoz or Sandoz's attorneys know of the existence, past or present, of any document or thing called for in a request, but such document or thing is not presently in Sandoz's possession, custody, or control or in the possession, custody, or control of its agents, representatives or attorneys, Sandoz shall so state in response to the request, identify such document or thing in response to the request and identify the individual in whose possession, custody, or control the document or thing was last known to reside.

9. Documents and things must be produced as they are maintained in the normal course of business and:

a) all associated file labels, file headings thereon and file folders shall be produced together with the responsive documents from each file;

b) all documents that cannot be legibly copied shall be produced in their original form; otherwise, Sandoz may produce photocopies; and

c) each page shall be given a discrete production number.

10. For the avoidance of doubt, each discovery request includes a request for documents to which Sandoz has a right of access.

DOCUMENTS AND THINGS TO BE PRODUCED

1. Documents and communications submitted to, filed with, or received from regulatory agencies and local authorities relating to Sandoz's Biosimilar Product, including the FDA, EMA and the local authorities in the countries where Sandoz's Biosimilar Product is manufactured or will potentially be manufactured, including any such documents submitted, filed or received by Sandoz Austria, Sandoz Slovenia or any manufacturer or potential manufacturer of Sandoz's Biosimilar Product.

2. The Common Technical Document for the Registration of Pharmaceuticals for Human Use filed by Sandoz with regulatory agencies, including the FDA and the EMA, relating to Sandoz's Biosimilar Product.

3. Documents and communications granting Sandoz a right of access to documents and communications relating to Sandoz's Biosimilar Product from any manufacturer or potential manufacturer of Sandoz's Biosimilar Product, including any contracts and agreements that grant the applicant for a marketing authorization of Sandoz's Biosimilar Product access to documents relating to the manufacture or expected manufacture of Sandoz's Biosimilar Product.

4. Documents sufficient to show, for all batches or lots of Sandoz's Biosimilar Product (both for drug product and drug substance) that have been manufactured and are planned to be manufactured, the purpose, reason, or rationale for manufacturing such drug product or drug substance, the timing of manufacturing, and size and quantity of lots or batches, and the location of manufacture.

5. Documents sufficient to show for Sandoz's Biosimilar Product that has been manufactured and is planned to be manufactured, all locations at which inventory of such product

is being stored or planned to be stored, the most current stock levels at each location, including by vial or syringe size and quantity, and the ultimate destination country for such product.

6. Any batch records (including appendices) relating to Sandoz's Biosimilar Product.

7. Any supplier records (including appendices) relating to Sandoz's Biosimilar Product.

8. Any lot releases (including appendices) relating to Sandoz's Biosimilar Product.

9. Documents and communications referring to any method by which the glycan content and/or the glycosylation profile of Sandoz's Biosimilar Product is controlled or manipulated, including documents sufficient to show the development of any such method.

10. Documents and communications referring to any analyses, testing or investigation of the glycan content of Sandoz's Biosimilar Product, including glycan maps, data for the glycosylation level and/or glycosylation profile for every batch or lot of Sandoz's Biosimilar Product produced and any studies that investigate the impact of any parameter on the glycosylation level and/or glycosylation profile of Sandoz's Biosimilar Product.

11. Cell culture medium batch preparation records and documents sufficient to show the process by which the cell culture media used in the manufacture or expected manufacture of Sandoz's Biosimilar Product is treated for viruses.

12. Documents and communications referring to any method by which the titer of denosumab antibody produced by the process used, or expected to be used, in the manufacture of Sandoz's Biosimilar Product is improved, controlled or manipulated by the composition of the cell culture media, including documents sufficient to show the development of any such method

and any studies that investigate the impact of modifications to the composition of the cell culture media on the titer of denosumab antibody produced.

13. Documents and communications referring to any method by which the viability of the cells grown in the cell culture medium that are used or expected to be used in the manufacture of Sandoz's Biosimilar Product is improved, controlled or manipulated by the composition of the cell culture media, including documents sufficient to show the development of any such method and any studies that investigate the impact of modifications to the composition of the cell culture media on cell viability.

14. Documents and communications sufficient to show the composition of the cell culture media used or expected to be used in the manufacture of Sandoz's Biosimilar Product, including the composition of the cell culture media or raw material used therein with respect to glucose, metabolites, vitamins, salts, metal ions, peptones, amino acids and dipeptides.

15. Documents and communications referring or relating to any method by which the oxidation state of Sandoz's Biosimilar Product is controlled or manipulated, including documents sufficient to show the development of any such method and documents referring to any method by which Sandoz's Biosimilar Product is subjected to charged depth filtration.

16. Documents and communications referring to any analyses, testing or investigation of the oxidation state of Sandoz's Biosimilar Product, including any studies that investigate the impact of any parameter on the oxidation state of Sandoz's Biosimilar Product.

17. Documents and communications referring to any method by which the flow rate of any solution of Sandoz's Biosimilar Product and/or any cell culture media used in the manufacture or expected manufacture of Sandoz's Biosimilar Product is controlled or manipulated, including any process flow diagram of the manufacturing process, any export report from the

automation software that shows the automation control strategy for the process to manufacture Sandoz's Biosimilar Product, and any design document or control strategy summary document for that automation software .

18. Any documents relating to the specification or schematics of any equipment used in any method by which Sandoz's Biosimilar Product is manufactured or expected to be manufactured or any step in any such method, including any documents relating to the specification or schematics of any purification, chromatography, filtration, ultrafiltration, charged depth filtration, viral filtration, tangential flow filtration, viral decontamination and sterilization equipment used in the manufacture or potential manufacture of Sandoz's Biosimilar Product.

EXHIBIT B

AO 88A (Rev. 12/13) Subpoena to Testify at a Deposition in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Delaware

Amgen Inc.	)	
Plaintiff	)	
v.	)	Civil Action No.
Sandoz Inc.	)	
Defendant	)	

SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To: Persons most knowlegeable at Sandoz Inc.
C/O Corporation Services Company, 251 Little Falls Drive, Wilmington, Delaware 19808

(Name of person to whom this subpoena is directed)

☑ *Testimony:* **YOU ARE COMMANDED** to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization, you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about the following matters, or those set forth in an attachment:
See Attachment A hereto

Place:	Date and Time:
	06/13/2023 9:00 am

The deposition will be recorded by this method: Stenographically and by videotape

❒ *Production:* You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and must permit inspection, copying, testing, or sampling of the material:

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 05/09/2023

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

/s/ Brian P. Egan
Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing *(name of party)* Amgen Inc., who issues or requests this subpoena, are:
Brian P. Egan (#6227); began@morrisnichols.com; 1201 North Market Street; P.O. Box 1347; Wilmington, DE 19899-1347

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this subpoena for *(name of individual and title, if any)* _____ on *(date)* _____ .

❒ I served the subpoena by delivering a copy to the named individual as follows: _____

_____

_____ on *(date)* _____ ; or

❒ I returned the subpoena unexecuted because: _____

_____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of $ _____ .

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc.:

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

(1) ***For a Trial, Hearing, or Deposition.*** A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) ***For Other Discovery.*** A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) ***Avoiding Undue Burden or Expense; Sanctions.*** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) ***Command to Produce Materials or Permit Inspection.***

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) ***Quashing or Modifying a Subpoena.***

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) ***Producing Documents or Electronically Stored Information.*** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) ***Claiming Privilege or Protection.***

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

For access to subpoena materials, see Fed. R. Civ. P. 45(a) Committee Note (2013).

ATTACHMENT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE THE APPLICATION OF AMGEN INC.	)	Misc. Case. No. _____

SUBPOENA TO SANDOZ INC. TO PRODUCE DEPOSITION TESTIMONY IN A CIVIL ACTION

DEFINITIONS AND INSTRUCTIONS

The following definitions are applicable to the deposition topics that are the subject of this subpoena:

1. The terms "you," "your," and "Sandoz" mean Sandoz Inc., and any parent, subsidiary, member and/or affiliated entity, past or present, of Sandoz, and any person or entity, past or present, acting on behalf of Sandoz, including, but not limited to, each of its present and former managers, officers, executives, directors, employees, attorneys, agents and/or representatives.

2. "Amgen" means Amgen Inc.

3. "Sandoz Austria" means collectively, jointly, and severally Sandoz GmbH and its officers, directors, representatives, employees, agents, partners, corporate parents, subsidiaries, affiliates, predecessors and successors, including any entities or persons acting on behalf of Sandoz Austria.

4. "Sandoz Slovenia" means collectively, jointly, and severally Lek Pharmaceuticals d.d. (Lek farmacevtska družba d.d.) and/or Novartis Pharmaceutical Production

d.o.o. (Novartis farmacevtska priozvodnja d.o.o.) and their officers, directors, representatives, employees, agents, partners, corporate parents, subsidiaries, affiliates, predecessors and successors, including any entities or persons acting on behalf of Sandoz Slovenia.

5. "Prolia®" means Amgen's product that contains the RANKL inhibitor antibody denosumab that is marketed under the Prolia brand name.

6. "XGEVA®" means Amgen's product that contains the RANKL inhibitor antibody denosumab that is marketed under the XGEVA brand name.

7. "Sandoz's Biosimilar Product" means any and all denosumab that Sandoz develops, manufactures, markets, or sells, or seeks to develop, manufacture, market, or sell, including denosumab products that are biosimilar to Prolia® and/or XGEVA®.

8. "EMA" means the European Medicines Agency.

9. "FDA" means the U.S. Food and Drug Administration.

10. "Document" shall be defined and construed in the broadest possible sense by Rule 34(a) of the Federal Rules of Civil Procedure and other applicable Rules, and includes papers of all kinds and non-paper information storage means, including by way of example and without limitation, originals and copies, however made, of letters, memoranda, notes, computer generated data, calendars, records, minutes, studies, reports, notebooks, messages, telegrams, ledgers, legal instruments, contracts (whether draft or final), agreements (whether draft or final), drawings, secretarial notes, work pads, diaries, films, tapes, videotapes, CD's, CVD's, pictures, photographs, books, pamphlets, publications, advertisements, sales literature, brochures, manuals, price lists, computer files, announcements, electronic mail messages, or any other writings, records, or tangible objects produced or reproduced mechanically, electrically, electronically,

photographically, or chemically. A draft or non-identical copy is a separate document within the meaning of this term.

11. "Communication" shall have the broadest possible meaning and shall include, without limitation, any transmission of information by one or more persons or entities and/or between two or more persons or entities by any means, including but not limited to all documents reflecting, recording, reporting, or memorializing or purporting to reflect, record, report, or memorialize any such communication.

12. The term "thing" means any physical specimen or other tangible item other than a document.

13. The terms "referring to" or "relating to" shall encompass the full scope allowed under Rule 26 of the Federal Rules of Civil Procedure, and mean in any way, directly or indirectly, regarding, considering, constituting, covering, defining, describing, involving, underlying, modifying, amending, confirming, mentioning, endorsing, recording, evidencing, pertaining to, referring to, reflecting, relating to, representing, supporting, qualifying, terminating, revoking, canceling, negating, concerning or having any connection with the matter discussed.

14. The terms "and" and "or" shall be interpreted liberally as conjunctive, disjunctive, or both so that the fullest disclosure of information is achieved.

15. The term "all" means all and each and the term "each" means each and all so that the fullest disclosure of information is achieved.

16. The singular includes the plural and the plural includes the singular so that the fullest disclosure of information is achieved.

17. The term "including" means including, but not limited to.

18. Sandoz is requested to respond within 21 days from the date of service of this subpoena and the Court's order authorizing service of this subpoena.

TOPICS

TOPIC NO. 1:

Documents and communications submitted to or received from regulatory agencies and local authorities relating to Sandoz's Biosimilar Product, including the FDA, EMA and the local authorities in the countries where Sandoz's Biosimilar Product is manufactured or will potentially be manufactured, including any such documents or communications submitted or received by Sandoz Austria, Sandoz Slovenia or any manufacturer or potential manufacturer of Sandoz's Biosimilar Product.

TOPIC NO. 2:

The Common Technical Document for the Registration of Pharmaceuticals for Human Use filed by Sandoz with regulatory agencies, including the FDA and the EMA, relating to Sandoz's Biosimilar Product.

TOPIC NO. 3:

Any right of access granted to Sandoz to documents and communications relating to Sandoz's Biosimilar Product from any manufacturer or potential manufacturer of Sandoz's Biosimilar Product, including any contracts and agreements that grant the applicant for a marketing authorization of Sandoz's Biosimilar Product access to documents relating to the manufacture or expected manufacture of Sandoz's Biosimilar Product.

TOPIC NO. 4:

For all batches or lots of Sandoz's Biosimilar Product (both for drug product and drug substance) that have been manufactured and are planned to be manufactured, the purpose,

reason, or rationale for manufacturing such drug product or drug substance, the timing of manufacturing, and size and quantity of lots or batches, and the location of manufacture.

TOPIC NO. 5:

All locations at which inventory of Sandoz's Biosimilar is being maintained, and the most current stock levels at each location, including by vial or syringe size and quantity.

TOPIC NO. 6:

Any batch records (including appendices) relating to Sandoz's Biosimilar Product.

TOPIC NO. 7:

Any supplier records (including appendices) relating to Sandoz's Biosimilar Product.

TOPIC NO. 8:

Any lot releases (including appendices) relating to Sandoz's Biosimilar Product.

TOPIC NO. 9:

Any method by which the glycan content and/or the glycosylation profile of Sandoz's Biosimilar Product is controlled or manipulated, including the development of any such method.

TOPIC NO. 10:

Any analyses, testing or investigation of the glycan content of Sandoz's Biosimilar Product, including glycan maps, data for the glycosylation level and/or glycosylation profile for every batch or lot of Sandoz's Biosimilar Product produced and any studies that investigate the impact of any parameter on the glycosylation level and/or glycosylation profile of Sandoz's Biosimilar Product.

TOPIC NO. 11:

Cell culture medium batch preparation records and the process by which the cell culture media used in the manufacture or expected manufacture of Sandoz's Biosimilar Product is treated for viruses.

TOPIC NO. 12:

Any method by which the titer of denosumab antibody produced by the process used, or expected to be used, in the manufacture of Sandoz's Biosimilar Product is improved, controlled or manipulated by the composition of the cell culture media, including the development of any such method and any studies that investigate the impact of modifications to the composition of the cell culture media on the titer of denosumab antibody produced.

TOPIC NO. 13:

Any method by which the viability of the cells grown in the cell culture medium that are used or expected to be used in the manufacture of Sandoz's Biosimilar Product is improved, controlled or manipulated by the composition of the cell culture media, including the development of any such method and any studies that investigate the impact of modifications to the composition of the cell culture media on cell viability.

TOPIC NO. 14:

The composition of the cell culture media used or expected to be used in the manufacture of Sandoz's Biosimilar Product, including the composition of the cell culture media or raw material used therein with respect to glucose, metabolites, vitamins, salts, metal ions, peptones, amino acids and dipeptides.

TOPIC NO. 15:

Any method by which the oxidation state of Sandoz's Biosimilar Product is controlled or manipulated, including the development of any such method and documents referring to any method by which Sandoz's Biosimilar Product is subjected to charged depth filtration.

TOPIC NO. 16:

Any analyses, testing or investigation of the oxidation state of Sandoz's Biosimilar Product, including any studies that investigate the impact of any parameter on the oxidation state of Sandoz's Biosimilar Product.

TOPIC NO. 17:

Any method by which the flow rate of any solution of Sandoz's Biosimilar Product and/or any cell culture media used in the manufacture or expected manufacture of Sandoz's Biosimilar Product is controlled or manipulated.

TOPIC NO. 18:

The specification or schematics of any equipment used in any method by which Sandoz's Biosimilar Product is manufactured or expected to be manufactured or any step in any such method, including the specification or schematics of any purification, chromatography, filtration, ultrafiltration, charged depth filtration, viral filtration, tangential flow filtration, viral decontamination and sterilization equipment used in the manufacture or potential manufacture of Sandoz's Biosimilar Product.

TOPIC NO. 19:

The subject matter, content, and authenticity of all documents and things produced by Sandoz in response to Amgen's document requests specified in Attachment A to Amgen's document subpoena.